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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,434	03/15/2001	Glenn McGall	2719.2017-001	6484

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EXAMINER

EPPS, JANET L

ART UNIT PAPER NUMBER

1635

DATE MAILED: 05/28/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/810,434

Applicant(s)

MCGALL ET AL.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-14-03 has been entered.

### ***Response to Amendment***

2. The Declaration under 37 CFR 1.132 filed 3-14-03 is not sufficient to overcome the rejection of claims 1-17 based upon 35 USC 103(a). The results provided in the McGall Declaration provides results from experiments based upon the use methods set forth in a reference that was published after the filing date of the instant application, and it is unclear if the methods set forth in the McGall et al. (2002) publication actually represent the conditions set forth for practicing the claimed method as set forth in the specification as filed.

The data provided in the Declaration is set forth in Average hybridization Signal Intensity, however there is no data provided regarding the actual range of hybridization signal intensities observed during each of these experiments. In order to make an accurate determination as to whether or not the data presented by the McGall Declaration is actually "unexpected," the actual range of hybridization intensities observed, and margin of error in each experiment would be necessary in order to make a proper assessment of this data. Moreover, the results provided in the McGall Declaration provides higher detectable signal when using a concentration of 0.02M, however there is no data provided which indicates that iodine

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concentrations having values ranging from about 0.005 M to about 0.05M would have unexpected hybridization intensity values as compared to the commonly used concentrations of about 0.1 M iodine in the claimed method. Since the margin of error is not provided for the observed values of hybridization intensity, absent evidence to the contrary, the values observed using a concentrations of 0.1M iodine in the claimed method would not be considered statistically different from those observed using 0.01M, 0.02M or 0.05M.

Furthermore, since the specification as filed does not provide a clear definition of the term "about" as recited in the claimed ranges, the metes and bounds of the range "from about 0.005M to about 0.05M," is unclear. The McGall Declaration does not provide any evidence that concentrations that are "about 0.005" or "about 0.10M" would produce unexpected results when practicing the claimed method. At best, it appears that the McGall Declaration provides unexpectedly higher hybridization intensity values for only one concentration, 0.02M.

***Claim Rejections - 35 USC § 103***

3. Claims 1-17 remain rejected and claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Earhart et al. in view of McGall et al., for the reasons of record set forth in the Official Actions mailed 12-17-2001, 7-03-02, and those reasons set forth in the above discussion of the McGall Declaration.

*Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 18-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter Rejection).

Claim 18 recites the method of claim 5, wherein from about 0.01M to about 0.05 M iodine is present in the aqueous solvent mixture. Claim 19 recites the method of claim 18, wherein from about 0.02 M to about 0.05 M iodine is presenting the aqueous solvent mixture. The specification as filed provides only support for the range of from about 0.005 to about 0.05 M of iodine to be used in the claimed methods. There is no express support for the ranges of from about 0.01M to about 0.05M or from about 0.02M to about 0.05M iodine. Although, these ranges are encompassed within the range of from about 0.005 to about 0.05M, there is no express support in the specification as-filed for the limitation "from about 0.02M" or "from about 0.01M." These limitations are considered new matter since one of skill in the art would not consider these limitations to be inherently supported by the discussion in the original disclosure. See MPEP § 2163.06, which states "The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement."

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Applicants must remove the new matter set forth in claims 18-19 in response to this Office Action.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-19 recite the limitations "from about 0.005M to about 0.05 M," "from about 0.01M to about 0.05M," and "from about 0.02M to about 0.05M." The specification as filed does not provide a definition of the term "about" as set forth in claimed ranges. One of ordinary skill in the art would not be able to ascertain the full scope of the claimed invention without the definition of the term. Due to the ambiguity regards the scope of the ranges recited in the instant claims, Applicants fail to provide sufficient warning to the ordinary artisan as how to avoid infringement of the claimed invention.

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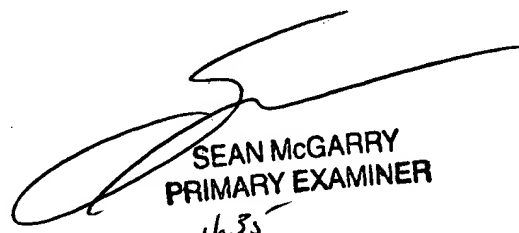
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, and Thurs-Fr, 9-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford  
Examiner  
Art Unit 1635

*JLE*  
May 22, 2003

  
SEAN MCGARRY  
PRIMARY EXAMINER  
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